

### **REMARKS**

Claims 1-26 are pending.

Claims 1-26 are pending after entry of the amendments set forth herein.

Claims 1-26 were examined.

Claims 1-26 were rejected and claims 11 and 20-25 were objected to.

Claim 7 has been cancelled and claims 1, 11, 17, and 20-25 have been amended. Please replace claims 1, 11, 17, and 20-25 with the clean versions provided above.

Corrections to Figure 2 have been proposed.

The specification has been amended to include reference to element 50 of corrected Figure 2.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

### **CLAIM OBJECTIONS**

The Examiner has objected to claim 11, stating that carbon and doped indium oxide are not metals. Applicants have amended claim 11 to delete the word "metal" and replace it with the word "material". Accordingly, the Applicants respectfully request that this rejection be withdrawn as no longer appropriate.

### **OBJECTION TO DRAWINGS**

The Examiner objected to the drawings stating that the ingress channels of claim 6 are not shown in the drawings. In response thereto, the Applicants have filed, concurrently herewith, a Request for Approval of Proposed Drawing Changes, together with a copy of Figure 2 attached thereto. The change in response to the Examiner's objection is indicated in red ink on the attached copy of Figure 2. The only change that has been proposed in response to this objection is to add channels that merge into a single channel. Review and approval of the attached proposal is respectfully requested. The Examiner is further requested to indicate such approval in the next Office Action or Notice of Allowance. In view of the concurrently filed request, the Examiner is respectfully requested to reconsider and withdraw the objection to the drawings as being no longer appropriate.

**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 17-20 have been rejected under 35 U.S.C. §112, second paragraph. The Examiner states that the phrase "said metallic electrodes" does not have sufficient antecedent basis. The Applicants have amended claim 17, from which claims 18-20 depend, to cancel the word "metallic" and add the word "opposing" in place thereof, where antecedent basis for "opposing electrodes" may be found in claim 17. Accordingly, the Applicants respectfully request that this rejection be withdrawn as no longer appropriate.

**REJECTION UNDER 35 U.S.C. §103(a)**

Claims 1, 2, 4, 16 and 24 have been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538). The Applicants respectfully submit that claims 1, 2, 4, 16 and 24 as amended are not unpatentable under 35 U.S. C. §103(a) over the Derwent abstract and Figure 1 of Schlibi (EP 1167538).

The M.P.E.P. provides clear guidance on the requirements of a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

M.P.E.P. § 2142.

Thus, the cited reference or combination of references must teach or suggest all of the limitations of the claimed invention for the claimed invention to be rendered obvious over the reference. Claim 1, from which claims 2, 4 and 16 depend, and claim 24, as amended, recite a test strip having a plurality of reaction zones, where a reagent composition is present in each of the reaction zones and at least one of the reagent compositions is a redox reagent system.

However, the Derwent abstract and Figure 1 of Schlibi (EP 1167538) do not teach or suggest a test strip having a plurality of reaction zones, where a reagent composition is present in each of the

reaction zones and at least one of the reagent compositions is a redox reagent system. As the cited reference fails to teach or suggest all of the claimed limitations, a proper *prima facie* case of obvious cannot be made for at least this reason. Accordingly, the Applicant respectfully requests that this rejection be withdrawn.

Claims 1, 2, 4, 16 and 24 have been rejected under 35 USC §103(a) as being unpatentable over Hodges et al. (U.S. 6,413,410 B1). However, the Applicants respectfully submit that Hodges et al. is not a proper reference as the instant invention and Hodges et al. were commonly owned at the time the invention was made. As evidence of this common ownership, the Applicants direct the Examiner to the Notice of Recordation and Assignment Document related to the instant application, which was recorded on 07/16/2002, reel/frame 013096/0416. The Applicants are herewith submitting a copy of the document for the Examiner's reference.

Accordingly, for at least the reason that the cited reference is not a proper reference, the Applicants respectfully request that this rejection be withdrawn as no longer appropriate.

Claims 1, 2, 4, 7-20 and 24 have been rejected under 35 USC §103(a) as being unpatentable over Bergkuist et al. (U.S. 6,123,820) in view of Hodges et al. (U.S. 6,413,410 B1). For reasons analogous to those described above in regard to Hodges, et al., i.e., that Hodges et al. is not a proper reference as the instant invention and Hodges et al. were commonly owned at the time the invention was made, the Applicants submit that this rejection cannot be sustained for at least this reason and thus respectfully request that this rejection be withdrawn.

Claim 3 has been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Yee (U.S. 5,672,256). As described above, the Derwent abstract and Figure 1 of Schlibi do not teach or suggest a test strip having a plurality of reaction zones, where a reagent composition is present in each of the reaction zones and at least one of the reagent compositions is a redox reagent system, as recited by claim 1 from which claim 3 depends. As such, the Derwent abstract and Figure 1 of Schlibi fail to teach or suggest all of the claimed limitations. As Yee is cited solely for the use of the same reagent composition in reaction zones, Yee fails to make

up the deficiencies of the Derwent abstract and Figure 1 of Schlibi. Accordingly, for at least this reason, the Applicants submit that a proper *prima facie* case of obviousness cannot be made and thus respectfully request that this rejection be withdrawn.

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Claims 7-15 have been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Hodges et al. (U.S. 6,413,410 B1). Claim 7 has been cancelled. In regards to claims 8-15, the Applicants submit that for reasons analogous to those described above in regard to Hodges, et al., i.e., that Hodges et al. is not a proper reference as the instant invention and Hodges et al. were commonly owned at the time the invention was made, the Applicants submit that for at least this reason this rejection cannot be sustained and thus respectfully request that this rejection be withdrawn.

Claims 17-20 have been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Hodges et al. (U.S. 6,413,410 B1). For reasons

analogous to those described above in regard to Hodges, et al., i.e., that Hodges et al. is not a proper reference as the instant invention and Hodges et al. were commonly owned at the time the invention was made, the Applicants submit that for at least this reason this rejection cannot be sustained and thus respectfully request that this rejection be withdrawn.

Claims 21 and 23 have been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Leader et al. (U.S. 5,421,981). As described above, the Derwent abstract and Figure 1 of Schlibi (EP 1167538) do not teach or suggest a test strip having a plurality of reaction zones, where a reagent composition is present in each of the reaction zones and at least one of the reagent compositions is a redox reagent system, as recited in claim 21 from which claim 23 depends. As such, the Derwent abstract and Figure 1 of Schlibi fail to teach or suggest all of the claimed limitations. As Leader et al. is cited solely for the use of a kit for determining the concentration of an analyte in a sample comprising a means for obtaining a sample and an analyte standard, Leader et al. fail to make up the deficiencies of the Derwent abstract and Figure 1 of Schlibi. Accordingly, for at least this reason, the Applicants submit that a proper *prima facie* case of obviousness cannot be made and thus respectfully requests that this rejection be withdrawn.

Claim 22 has been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Leader et al. (U.S. 5,421,981) and further in view of Guruswamy et al. (5,004,583). As described above, the Derwent abstract and Figure 1 of Schlibi (EP 1167538) do not teach or suggest a test strip having a plurality of reaction zones, where a reagent composition is present in each of the reaction zones and at least one of the reagent compositions is a redox reagent system, as recited in claim 21, from which claim 22 depends. As such, the Derwent abstract and Figure 1 of Schlibi fail to teach or suggest all of the claimed limitations. As Leader et al. is cited solely for the use of a kit for determining the concentration of an analyte in a sample comprising a means for obtaining a sample and an analyte standard, and Guruswamy et al. is cited solely for the use of a lance, Leader et al. and Guruswamy et al. fail to make up the deficiencies of the Derwent abstract and Figure 1 of Schlibi. Accordingly, for at least this reason, the Applicants submit that a proper *prima facie* case of obviousness cannot be made and thus respectfully requests that this rejection be withdrawn.

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submit that for at least this reason this rejection cannot be sustained and thus respectfully request that this rejection be withdrawn.

Claims 25 and 26 have been rejected under 35 USC §103(a) as being unpatentable over the Derwent abstract and Figure 1 of Schlibi (EP 1167538) in view of Leader et al. (U.S. 5,421,981). As described above, the Derwent abstract and Figure 1 of Schlibi (EP 1167538) do not teach or suggest a test strip having a plurality of reaction zones, where a reagent composition is present in each of the reaction zones and at least one of the reagent compositions is a redox reagent system, as recited in claim 23 from which claims 25 and 26 depends. Accordingly, the Derwent abstract and Figure 1 of Schlibi fail to teach or suggest all of the claimed limitations. As Leader et al. is cited solely for the use of a kit for determining the concentration of an analyte in a sample comprising a means for obtaining a sample and an analyte standard, Leader et al. fail to make up the deficiencies of the Derwent abstract and Figure 1 of Schlibi. Accordingly, for at least this reason, the Applicants submit that a proper *prima facie* case of obviousness cannot be made and thus respectfully requests that this rejection be withdrawn.

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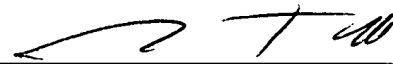
**CONCLUSION**

In view of the remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, reference no. LIFE-015.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 12/3/02

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION**

Please replace the paragraph on page 7, beginning on line 4 with the following amended paragraph:

(Amended) In certain embodiments of the invention, each reaction zone or area has its own distinct ingress and egress channel. As such, the number of different ingress channels in these embodiments equals the number of different reaction areas of the strip. In yet other embodiments, two or more of the ingress channels may merge into a single channel prior to exit from the strip (see for example channel 50 of Figure 2), such that fluid can be introduced into two or more different reaction areas from a single entry port. In other words, a single ingress channel may branch into two or more sub-channels that enter different reaction zones of the strip. The spacer layer of the subject strips is designed to provide for the desired ingress channel pattern, e.g., separate or merged channels.

**IN THE CLAIMS**

Please cancel claim 7.

Please amend claims 1, 11, 17, 20, 21, 22, 23, 24 and 25 as follows:

1. (Amended) An electrochemical test strip comprising:
  - (a) a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer; and
  - (d) a reagent composition present in each of said reaction zones; wherein at least one of said reagent compositions is a redox reagent system.
11. (Amended) The electrochemical test strip according to Claim 1, wherein at least one of said electrodes comprises a ~~metal~~ material selected from the group consisting of: gold, palladium, silver, iridium, carbon, platinum, nichrome, doped indium tin oxide and stainless steel.

17. (Amended) A method of determining the concentration of an analyte in a physiological sample, said method comprising:

- (a) applying said physiological sample to an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition present in each of said reaction zones;
- (b) detecting an electrical signal in said reaction zone using said ~~metallie~~ opposing electrodes; and
- (e) relating said detected electrical signal to the amount of said analyte in said sample.

~~20~~ 21. (Amended) A kit for use in determining the concentration of an analyte in a physiological sample, said kit comprising:

- (a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition present in each of said reaction zones; and
- (b) at least one of:
  - (i) a means for obtaining said physiological sample; and
  - (ii) an analyte standard.

~~21-22~~. (Amended) The kit according to Claim ~~20-21~~, wherein said means for obtaining said physiological sample is a lance.

~~22-23~~. (Amended) The kit according to Claim ~~20-21~~, wherein said kit further comprises a meter.

~~23-24~~. (Amended) A system for use in determining the concentration of an analyte in a physiological sample, said system comprising:

- (a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition present in each of said reaction zones-, wherein at least one of said reagent compositions is a redox reagent system; and
- (b) a meter.

~~24-25~~. (Amended) The system according to Claim ~~23-24~~, wherein said system further comprises a means for obtaining said physiological sample.

~~25~~26. (Amended) The system according to Claim ~~23~~24, wherein said system further comprises an analyte standard.